

## **REMARKS**

Claims 1-9 and 56-59 are pending in the present application.

Claim 2 has been amended for clarity, and is fully supported by the specification as filed, for example, at page 13, paragraph [0048]. No new matter is added.

### ***Rejection Under 35 U.S.C. § 103(a)***

Claims 1-9 and 56-59 stand rejected for alleged obviousness over U.S. Pat. No. 7,081,122 to Reiley (“the Reiley patent”) in view of U.S. Pat. No. 6,671,561 to Moaddeb (“the Moaddeb patent”). Applicants respectfully submit that the claims are not rendered obvious by the respective or combined teachings of the cited references at least because (1) the Office’s conclusion is not based on any particular findings that one skilled in the art would have selected the Reiley patent and the Moaddeb patent for combination, and (2) even if one skilled in the art would have been motivated to combine the cited references, the combination fails to teach or suggest any claimed invention.

First, the cited references cannot fairly be said to render Applicants’ claimed inventions obvious because there is no evidence of record demonstrating that those of ordinary skill in the art would have been motivated to actually combine the references’ respective teachings or to do so in a way that would have produced a claimed invention. The Office posits only a single rationale as to why it would have allegedly been obvious to one skilled in the art to modify the tip of the catheter of the Reiley patent by providing a “porous layer” as disclosed by the Moaddeb patent: “to prevent damage to the interior walls of the heart or blood vessels” (10/16/07 Office Action at page 3). However, as clearly provided in the Moaddeb patent, the ability of the catheter to reduce the probability of damage to vascular physiology is not attributable to the “porous layer” disclosed in the Moaddeb patent, but rather to other features of the disclosed catheter, such as the “hydrogel layer” (*see* Moaddeb patent at col. 4, lines 1-6). In fact, the purpose of the “porous layer” is to improve a feature that is *unique to ablation catheters* (*i.e.*, the dissipation of heat during ablation; *see* Moaddeb patent at col. 5, lines 9-10) and is *irrelevant* to delivery systems such as the device disclosed

in the Reiley patent. Thus, one skilled in the art would not modify the Reiley patent by including a “porous layer” as taught by the Moaddeb patent either “to prevent damage to the interior walls of the heart or blood vessels”, as proposed by the Office, or for any other reason.

The Office posits no other evidence or reasoning as to why those of ordinary skill would have been motivated to combine the disclosure of the Reiley patent with that of the Moaddeb patent. Absent evidence or reasoning based on objective factors demonstrating that the posited modifications of the cited references would have been ones that those of ordinary skill in the art actually would have been motivated to make, the rejection of claims 1-9 and 56-59 for alleged obviousness is improper and should be withdrawn. *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. June 28, 2007) (confirming that obviousness cannot be established based on a combination of references absent “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does”) (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007)). See also May 3, 2007 Memo from Margaret A. Focarino, Deputy Commissioner for Patent Operations, U.S. Patent Office (“it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.”) (commenting on *KSR Int'l Co.*, 127 S. Ct. 1727 (2007)).

Second, even if one skilled in the art would have been motivated to combine the cited references, the resulting combination would not result in any claimed invention. Although the Office concedes that the Reiley patent does not teach a catheter having a substantially rigid high-porosity tip, the Office alleges that the Moaddeb patent evidences the use of a catheter having a “high-porosity tip.” The Applicants respectfully submit that this conclusion is factually incorrect. Moaddeb does not describe a “high-porosity tip” as presently claimed. *Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1353 (Fed. Cir. 1999) (“It is well-established that the first step in any [obviousness] analysis is to construe the claims of the invention to determine the subject matter for which patent protection is sought.”). Although Applicants recognize that limitations from the specification are not read into the claims, it is the case that claim terms are properly construed in light of the specification.

*Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (*en banc*). With regard to the “high-porosity tip” of the present invention, the specification provides as follows:

the distal end of the catheter may have a ***high-porosity tip*** 98 (see Figure 10), or directional diffuser . . . The directional diffuser 98 permits uniform, multi-directional delivery of a restorative or injectable material.

(specification at page 12, lines 7-12; emphasis added). When considered in light of the specification, it becomes clear that the “high-porosity tip” of the present invention may be a structure that permits multi-directional delivery of a material from the catheter. In contrast, the Moaddeb patent describes an ablation catheter having a tip electrode 30 that is made of an electrically-conductive base material comprising, for example, a metal or a ceramic (see col. 3, lines 32-43; *see also* FIG. 3, reference numeral 30). The tip electrode 30 represents a “dead end,” *i.e.*, it is a solid, non-porous piece of material that does not include structures necessary to permit the passage of material from an internal space within the catheter. The “porous layer” is merely an electrically-conductive layer of material that is applied to the outer surface of the solid material comprising the tip electrode 30 (see Moaddeb patent at col. 4, lines 35-38). Therefore, the distal tip of the device disclosed in the Moaddeb patent comprises a nonporous tip electrode 30 that is coated with a layer of porous material. The presence of a porous overcoat on an otherwise nonporous tip does not convert the nonporous tip of the Moaddeb device to one having “high-porosity” as presently claimed. Indeed, the only similarity between the “porous layer” of the Moaddeb patent and the “high-porosity tip” of the present invention is partially overlapping nomenclature, *i.e.*, the word “porous”, which is not a proper basis for a *prima facie* obviousness rejection. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974) (to establish a *prima facie* case of obviousness, all claim limitations must be taught or suggested by the prior art).

Therefore, even if there were sufficient motivation for one skilled in the art to have combined the cited references in the manner proposed by the Office, the proposed combination would not produce any claimed invention. For at least these reasons, Applicants respectfully submit that the instant rejection under § 103(a) should be withdrawn.

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**PATENT**

***Conclusion***

The Applicants submit that the foregoing represents a *bona fide* attempt to advance the present case to allowance, and that the application is now in condition therefor. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 215-564-8918.

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